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10/612,517	07/02/2003	Marsella Jefferson	1111	3540
23545 7590 03/30/2007 KATHLEEN M HARLESTON THE HARLESTON LAW FIRM 909 TALL PINE ROAD MT PLEASANT, SC 29464			EXAMINER GOLLAMUDI, SHARMILA S	
			ART UNIT	PAPER NUMBER
			1616	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/612,517	Applicant(s) JEFFERSON, MARSELLA	
	Examiner Sharmila S. Gollamudi	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 16-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of Amendments and Remarks filed 1/12/07 is acknowledged. Claims 1-15 are directed to the elected invention. Claims 16-20 are withdrawn as being directed to a nonelected invention.

Response to Arguments Pertaining to the Rejections over DE '982 as the Primary Reference

Applicant argues that the references DE '982, Muller, Schultz, and Flender are nonanalogous art and is not related to the instant invention. Applicant argues that the test of obviousness is what the combined teachings of references would have suggested to a skilled artisan. Applicant argues that none of the cited references related to hair treatment for African-Americans.

Applicant's arguments filed 1/12/07 have been fully considered but they are not persuasive. It appears applicant has confused intended use and nonanalogous art. Claims 1-15 are directed to a composition and not the method of use of the composition. Thus, the patentability of the claims is based on the composition and not the method of use. The examiner points out that the recitation "for the treatment of hair" is a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Thus, the recitation "for the treatment of hair" does not impart a structural limitation and any composition comprising the claimed components and capable of being applied to the hair is sufficient to meet the claimed invention. The prior references cited by the examiner are directed to topical, pharmaceutical composition and DE '982, Muller, Schultz, and Flender are analogous art.

Applicant argues Muller teaches sterols and phospholipids to make a liposome. Applicant argues that the instant invention does not include sterols. Applicant there is no motivation to select lecithin as the liposome component and exclude the sterol component.

Firstly, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In instant case, the rejection is not to incorporate Muller's teaching in its entirety into DE '982. DE '982 clearly suggests a liposome *component* not a liposome itself. It is known in the art that lecithin is a conventional and routine liposome component. However, the examiner relies on Muller to demonstrate the state of the art to substantiate this. Muller teaches phosphatidylcholine (lecithin) is a preferred component to make a liposome. Muller clearly teaches on column 2, lines 60-65 that sterols are *additives*. Sterols are not critical to the formation of a liposome and rather function as a stabilizing additive. Again, the examiner points out that DE '982 suggests a liposome *component* not a liposome itself. Lastly, even arguing the entire liposome was incorporated, the examiner points out that the instant claim language, i.e. comprising, does not exclude other components such as sterols in the composition. The use of liposomes as vehicles are used to enhance the penetration of the active as taught by Muller on column 2, lines 25-40. Therefore, another motivation to combine the references and use a liposome comprising lecithin is to increase penetration of the active into the skin.

Applicant argues that that DE '982 and Muller do not suggest the instant ratios.

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The examiner points to DE '982's teachings of 30-60% of an ointment base, 1-10% of a liposome component, 2-20% water, 1-10% tea tree oil, 1-10% jojoba oil, and 0.5-10% lavender oil. More specifically, one of the examples teach 9.5% water, 2% tea tree oil, 1% jojoba oil, 2% lavender oil, and 60% of the ointment base which may be Vaseline. Thus, the amount of the essential oil and water is in an amount of 14.5% and the amount of ointment base is 60%. This falls within the claims ratio range.

Applicant argues that the instant claims exclude a surfactant and Grollier teaches an oil-soluble surfactant. Thus, applicant argues that a skilled artisan would not have been motivated to specifically exclude the surfactant taught in Grollier.

Again it is noted that applicant's arguments are based on the bodily incorporation of the secondary reference into the primary reference. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In instant case, the examiner only relies on Grollier to teach the functional equivalency between the claimed oils and the prior art's oil. DE '982 teaches the use of jojoba oil in the composition and Grollier teaches jojoba oil, almond oil, and grape seed oil are conventional oils used to treat the skin and scalp. Applicant has not argued the examiner's motivation and rather argues against the references individually. However, one cannot show nonobviousness by attacking references individually where the rejections are based on

combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Therefore, the rejection is maintained since applicant has not provided any persuasive arguments or a showing of unexpectedness to overcome the rejection based on obviousness.

Response to Arguments Pertaining to the Rejections over Jones as the Primary Reference

Applicant argues that Jones teaches a cream with oil of burdock and Flender teaches an ointment comprising cholesterol. Applicant argues that the examiner has used impermissible hindsight. Applicant argues that there is no motivation to use water and omit cholesterol and burdock root. Applicant argues that the instant invention adds a small amount of water while mixing at elevated temperatures to achieve a two-phase mixture. Applicant argues that Jones does not teach petroleum jelly.

Applicant's arguments filed 1/12/07 have been fully considered but they are not persuasive. Firstly, the examiner points out that Jones teaches petrolatum on column 1, line 33, which is another name for petroleum jelly. Again it is noted that applicant's arguments are based on the bodily incorporation of the secondary reference into the primary reference. In the instant rejection, Jones composition is clearly an emulsion with water-soluble components and oil-soluble components. Flender teaches the addition of water to an ointment having a base such as petrolatum to influence the viscosity of the composition. Therefore, the motivation to add water is to yield an ointment with a lower viscosity. Applicant has not addressed the examiner's motivation. Secondly, even *arguendo* that one incorporated the teachings of Flender into Jones, the examiner points out that the instant claim language does not exclude cholesterol and burdock. With regard to applicant's argument pertaining to the process of preparing the composition, the

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examiner points out that the instant claims are directed to composition claims and not the method of preparing the composition. Thus, arguments pertaining to the process of making the composition do not hold patentable weight.

Applicant argues that Hyldgaard teaches the use of surfactants and the instant claims exclude surfactants. Again it is noted that applicant's arguments are based on the bodily incorporation of the secondary reference into the primary reference. The examiner points out that Hyldgaard is relied upon for the specific teaching of functional equivalency of Jones vitamin E and the instantly claimed citric acid and the instantly claimed oils versus Jones's oils. Applicant has not addressed the examiner's motivation. Moreover, it is noted that applicant acquiesces that the oils are obvious variants.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 3 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's amendment to claim 3 to recite the ratio of the essential oil and water to petroleum jelly is about 1:2 to about 1:4 does not have support in the claims as originally or the instant specification. It is further noted that applicant has not pointed to support for the claimed

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limitation. If applicant contends there is support for said limitation, then the examiner requests applicant provide the specific page and line of said support.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4, 11-12, 14-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 depends on claim 1, wherein claim 1 requires about 2-20% lecithin. Claims 2 and 4 respectively are directed to the composition of claim 1, wherein the composition does not contain a surfactant. Thus, claim 2 and 4 respectively are vague and indefinite since lecithin is a known surfactant (note Wikipedia encyclopedia attached). Therefore, the claimed limitation directly contradicts the parent claim. Claims 11-12 and 14-15 are rejected under indefiniteness since they depend on an indefinite claim.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 3, and 6 under 35 U.S.C. 102(b) as being anticipated by Lachampt et al (3,846,546) is withdrawn in light of the amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 5, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 019800982 in view of Muller et al (4,954,345).

DE '982 teaches a medicinal ointment comprises an ointment base selected from at least one of lanolin, Vaseline, beeswax, or paraffin and water. The ointment further contains an active ingredient of (i) a liposome component; (ii) an ethereal oil of at least one of nutmeg oil, borage oil, jojoba oil, evening primrose oil, tea tree oil, or lavender oil. Examples 1 teaches a composition comprising 30-60% beeswax/lanolin; 1-10% of a liposome component; 1-10% tea tree oil; 1-10% jojoba oil; 0.5-10% lavender oil; and 2-20% water, among other components.

DE '982 does specify the liposome component.

Muller teaches a pharmaceutical preparation for external or transdermal application, which comprises a dispersion of liposomes, wherein said liposomes incorporate or enclose an active ingredient. Muller teaches liposomes are medicinal vehicles and are prepared from phospholipids, for example, lecithin. Muller teaches various methods may be employed to prepare the liposome preparations from the components of the liposomes, which are phospholipids. Particularly suitable phospholipids are phosphatidylcholines, such as lecithins (a

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naturally occurring group of phospholipids). See column 1, lines 20-35 and column 2, lines 55-65.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of DE '982 and Muller and utilize lecithin as the liposome component taught in DE '982. One would have been motivated to do so since Muller teaches phospholipids, such as lecithin, are conventional components used to make a liposomes. Therefore, although DE does not specify the liposome component, it would have been obvious to utilize a conventional and routinely used liposome component such as lecithin, to make the liposome. Note that with regard to DE '982 although the example utilizes lanolin or beeswax, it would have been obvious for a skilled artisan to substitute the exemplified ointment base (beeswax/lanolin? with Vaseline as suggested by DE '982 since DE teaches the use of beeswax, lanolin, *or* Vaseline as the base for the ointment.

Claims 7-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 019800982 in view of Muller et al (4,954,345) in further view of Schultz (20020082279).

The teachings of DE '982 and Muller have been delineated above. DE '982 teaches a composition for the treatment of psoriasis, eczema, and dermatitis comprising at least one ethereal oil of at least one of nutmeg oil, borage oil, jojoba oil, evening primrose oil, tea tree oil, or lavender oil. Examples 1 teaches a composition comprising 30-60% beeswax/lanolin; 1-10% of a liposome component; 1-10% tea tree oil; 1-10% jojoba oil; 1-10% borage oil, 0.5-10% lavender oil; and 2-20% water, among other components.

DE '982 does not teach the use of basil, peppermint, or sage oil respectively.

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Schultz teaches a topical composition for the treatment of a dermatologic diseases including psoriasis, dermatitis, and eczema, wherein the composition comprises at least one essential oil. see abstract and [0018]. Essential oils which have a direct skin effect include Peppermint, Chamomile, Cypress, Cajeput, Thyme, Clove Bud, Lavender, Clary Sage, Rosemary, and Basil, among others. See [011].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the above references and substitute the prior art's lavender oil with the instantly claimed oil (basil, peppermint, or sage respectively). One would have been motivated to do so with a reasonable expectation of success and similar results since Schultz teaches lavender oil, basil oil, peppermint, and sage oil are all essentials oils that treat skin disorders such as psoriasis, dermatitis, and eczema. Therefore, it would have been prima facie obvious for a skilled artisan to substitute one functionally equivalent essential oil with another functionally equivalent essential oil since the prior art establishes the functional equivalency of the instantly claimed essential oil(s) and the prior art's essential oil, in treating skin disorders.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over DE 019800982 in view of Muller et al (4,954,345) in further view of Grollier (4626529).

The teachings of DE '982 and Muller have been delineated above. DE '982 teaches a composition for the treatment of psoriasis, eczema, and dermatitis. Examples 1 teaches a composition comprising 30-60% beeswax/lanolin; 1-10% of a liposome component; 1-10% tea tree oil; 1-10% jojoba oil; 1-10% borage oil, 0.5-10% lavender oil; and 2-20% water, among other components.

DE '982 does not teach the instantly claimed grape seed oil.

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Grollier teaches an oily composition for the treatment of the skin and scalp. Grollier teaches vegetable oils that are suitable include almond oil, wheat germ oil, apricot-kernel oil, walnut oil, palm oil, pistachio oil, sesame oil, castor oil, soya oil, avocado oil, safflower oil, copra oil, hazelnut oil, olive oil, grape-seed oil, sunflower oil, colza oil, cade oil, maize germ oil, peach-kernel oil, and jojoba oil. see column 4, lines 14-20.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the above references and substitute the prior art's jojoba oil with the instantly claimed grape seed oil or almond oil, respectively. One would have been motivated to do so with a reasonable expectation of success and similar results since Grollier teaches jojoba oil, almond oil, and grape seed oil are all vegetable oils that are conventionally used in compositions for the treatment of the skin and scalp. Therefore, it would have been prima facie obvious for a skilled artisan to substitute one functionally equivalent vegetable oil with another functionally equivalent vegetable oil since the prior art establishes the functional equivalency of the instantly claimed oil(s) and the prior art's oil, in treating the skin.

Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 019800982 in view of Muller et al (4,954,345) in view of Grollier (4626529) in further view of Schultz (20020082279).

The teachings of DE, Muller, and Grollier have been set forth above.

DE '982 does not teach the use of rosemary or thyme oil respectively.

Schultz teaches a topical composition for the treatment of a dermatologic diseases including psoriasis, dermatitis, and eczema, wherein the composition comprises at least one essential oil. see abstract and [0018]. Essential oils which have a direct skin effect include

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Peppermint, Chamomile, Cypress, Cajeput, Thyme, Clove Bud, Lavender, Clary Sage, Rosemary, and Basil, among others. See [011].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the above references and substitute the prior art's lavender oil with the instantly claimed oil, rosemary or thyme respectively. One would have been motivated to do so with a reasonable expectation of success and similar results since Schultz teaches lavender oil, rosemary oil, and thyme oil are essential oils that treat skin disorders such as psoriasis, dermatitis, and eczema. Therefore, it would have been prima facie obvious for a skilled artisan to substitute one functionally equivalent essential oil with another functionally equivalent essential oil since the prior art establishes the functional equivalency of the instantly claimed essential oil(s) and the prior art's essential oil, in treating skin disorders.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over DE 019800982 in view of Muller et al (4,954,345) in view of Chang et al (5,942,233) in further view of Koulbanis et al (5,560,916).

The teachings of DE and Muller have been delineated above. DE teaches a medicinal ointment for the treatment of psoriasis, dermatitis, and eczema.

The references do not teach the use of apple cider in the composition.

Chang teaches a herbal composition to promote blood circulation. Chang teaches the incorporation keratin softening substance such as vinegar to soften the keratin layers and allow the drug to penetrate the skin easily. See column 5, lines 55-60 and column 6, lines 8-17. The keratin softening material is taught in an amount of 0.5-4%. See claim 2 and 3.

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Koulbanis teaches a cosmetic composition comprising vinegar. See abstract. Koulbanis discloses the prior art utilized vinegar as an antiseptic, for the treatment of psoriasis and eczema. See column 1, lines 35-50. Koulbanis teaches the properties of vinegar are due to the acetic acid. Koulbanis teaches several types of vinegar such as cider vinegar, lemon vinegar, blackberry vinegar and raspberry vinegar are suitable and regardless of its origin, vinegar has a natural acidity which is due principally to acetic acid, which makes up from 4 to 18% of its composition. Vinegar additionally comprises 10 inorganic salts, in particular those of zinc, potassium, lithium and sodium; sugars, in particular glucose, fructose and xylitol; ethanol, and vitamins (vitamins B and D in particular). See column 2, lines 25-44.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above references and further utilize vinegar in DE's composition. One would have been motivated to do so since Chang teaches the use of vinegar to soften keratin layers, allowing better penetration of active agents. Therefore, a skilled artisan would have been motivated to use vinegar for its penetration enhancing properties. Further, a skilled artisan would have expected success using vinegar from any source since Koulbanis teaches the effectiveness of vinegar is due to the acetic acid and the source of the vinegar is not critical since all vinegars have acetic acid and other essential components. Moreover, a skilled artisan would have reasonably expected success by the addition of vinegar to DE's composition since Koulbanis teaches the state of the art wherein it is known to utilize vinegar to treat skin disorders such as psoriasis and eczema for its antiseptic properties. Thus, a skilled artisan would have been further motivated to use vinegar for its antiseptic properties.

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Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones (5,116,607) in view of Flender (5,179,086) or Peffly (6,093,410).

Jones teaches hair dressing cream comprising 46% petrolatum (also known as petroleum jelly), 2.32% lecithin, 1.16% olive oil, 5.49% essential oil mixture (jojoba oil, coconut oil, sesame oil, wheat germ oil, castor oil, almond oil, and mink oil combined), PEG-75 lanolin that is 50% aqueous, 2.32% lecithin, 1% of a fragrance, among other components.

Jones does not teach the water in the composition.

Flender teaches a topical ointment to treat psoriasis comprising 20-40% Vaseline, 25-45% jojoba oil, 2-6% cholesterol, 2-8% beeswax, and 15-30% water. See column 3, lines 15-25. Flender teaches the use of Vaseline and jojoba oil as vehicles and the use of beeswax to influence the spreadability of the ointment. See column 2, lines 35-66. Flender teaches water is added to the composition to provide a low-viscosity. The amount of water utilized depends on the consistency desired. See column 3, lines 25-36.

Peffly teaches a personal care composition. Peffly teaches adding water to the composition when the viscosity of the system becomes very thick a portion of the water can be added to the system. The water is used in an amount sufficient to lower the viscosity enough in order to achieve good mixing.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Jones and Flender and further utilize water in Jones' cream composition. One would have been motivated to do so to decrease the viscosity of the composition and obtain the desired consistency of the composition as taught by Flender who demonstrates the state of art wherein it is known to add water to compositions to reduce viscosity

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of the composition. Further, Peffly is also cited since Peffly also demonstrates that is known in the art to add water to a composition to reduce its viscosity. The addition of water to Jones' composition and would not have a deleterious effect since Jones teaches the composition is in a cream form, which is an emulsified emulsion that comprises both oily components and aqueous components. Jones teaches the use of various water-soluble substances and water containing agents such as PEG-75 lanolin that is 50% aqueous. Therefore, a skilled artisan would have reasonably expected success with the modification.

Claims 4, 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones (5,116,607) in view of Flender (5,179,086) or Peffly (6,093,410) in further view of Hyldgaard (6342208).

The teachings of Jones, Flender, and Peffly have been delineated above. Jones teaches the use of vitamin E.

The references do not teach the use of citric acid or grape seed oil.

Hyldgaard teaches an oil-in-water emulsion for the treatment of skin and hair. Hyldgaard teaches the use of stabilizing agents for emulsions, such as antioxidants like citric acid, sorbic acid, benzoic acid, ascorbic acid, tartaric acid, and tocopherols (vitamin E). The examples utilize 0.5%. Further, Hyldgaard teaches suitable vegetable fats are avocado oil, coconut fat, cocoa butter, rapeseed oil, maize oil, sesame oil, olive oil, soybean oil, palm oil, grape seed oil, almond oil, linseed oil, peanut oil, walnut oil, tall oil, thistle seed oil, wheat germ oil, jojoba oil, castor oil, hydrogenated vegetable oils, and mixtures thereof.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the above references and substitute vitamin E with the instantly claimed

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citric acid. One would have been motivated to do so since Hyldgaard teaches emulsions require stabilizers such antioxidants including citric acid and tocopherol. Therefore, it would have been prima facie obvious for a skilled artisan to substitute one functionally equivalent emulsion stabilizer with another functionally equivalent emulsion stabilizer since the prior art establishes the functional equivalency of the instant stabilizer and the prior art's stabilizer. Additionally, it would have been obvious for a skilled artisan to substitute the prior art's oils (jojoba, sesame, wheat germ, almond or coconut oil) with the instantly claimed grape seed oil. One would have been motivated to do so with a reasonable expectation of success and similar results since Hyldgaard teaches grape seed, jojoba, sesame, wheat germ, almond, and coconut oil all are vegetable oils that may be used in compositions for the treatment of the skin and hair. Therefore, it would have been prima facie obvious for a skilled artisan to substitute one functionally equivalent vegetable oil with another functionally equivalent vegetable oil since the prior art establishes the functional equivalency of the instantly claimed oils and the prior art's oil, in treating hair.

With regard to claim 15, it is known that virgin olive oil and olive oil have the same essential components wherein the difference lies in the processing of the oil and taste. Thus, absent the unexpectedness of virgin olive oil versus olive oil, it would have been obvious to utilize either one depending on the desired type of olive oil in the *topical* composition.

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ziegler (5,310,556).

Ziegler teaches a cosmetic composition for dry skin. The composition comprises the critical ingredients of water in the preferably amount of 10-20%; petroleum jelly in the

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preferable amount of 0.5-30%; and lecithin in the preferably amount of 0.05-2%. See column 2, lines 15-47. Ziegler teaches sunflower seed oil in the preferable amount of 1-15% is a further essential component. Note this reads on essential oil. Further, Ziegler teaches the use of borage seed oil for its linoleic acid content in the amount of 0.001-5%. Note column 2, lines 50-62.

Although Ziegler teaches a similar ratio, the instant ratio is not specified. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance provided by Ziegler and manipulate the amounts of the essential oil/water to petroleum jelly ratio. One would have been motivated to do so with a reasonable expectation of success since Ziegler teaches the general range of each component claimed and the manipulation of each component within the given range provided by the prior art would yield the instant ratio. The reference teaches a range of 10-20% water; 0.5-30% petroleum jelly; and 1-15% sunflower oil. Therefore, the manipulation within these ranges would provide claimed ratio. Thus, for instance, if one utilized a range of 10% water, 15% sunflower oil, and 30% petroleum jelly, the instant ratio would be satisfied. It should be noted that "Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

With regard to claim 2, Ziegler teaches that lecithin, water, petroleum jelly, sterols, and sunflower oil are essential ingredients and other ingredients are optional. Therefore, although Ziegler teaches silicone oils are optional, it would have been obvious to a skilled artisan to

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exclude silicone oils with a reasonable expectation of success and similar results since this is not a critical element of the composition and it an optional additive.

It should be noted that the intended use of the composition is not given patentable weight since it does not impart a structural limitation to the composition.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ziegler (5,310,556) in further view of Enjolras (5,656,278).

The disclosure of Ziegler has been set forth above. Particularly, Ziegler teaches the use of borage seed oil for its linoleic acid content in the amount of 0.001-5% and preferably 0.01-2%.

Ziegler does not teach the use of grape seed oil.

Enjolras teaches a cosmetic composition comprising a source comprising linoleic acid for treating dry skin. See abstract. Enjolras teaches vegetable oils that are rich in linoleic acid are grapeseed oil, apricot seed oil, borage oil, almond oil, rapeseed oil, safflower oil, sunflower oil, etc. The oils are used in an amount of 0.01-30 and preferably 0.1-1%. see column 5, lines 30-55.

It would have been obvious to one of ordinary skill in the art at the time the invention was made combine the teachings of Ziegler and Enjolras and substitute the prior art's borage oil with the instant grapeseed oil. One would have been motivated to do so since Ziegler teaches the criticality of tiling borage oil is for its linoleic acid and Enjolras teaches vegetable oils that comprise linoleic acid include grapeseed oil and borage oil and are useful for treating dry skin. Therefore, it would have been prima facie obvious for a skilled artisan to substitute one functional equivalent oil with another equivalent oil since the prior art establishes the functional equivalency of both, i.e. both contain linoleic acid and may be used to treat dry skin.

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Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ziegler (5,310,556) in further view of Lin et al (5,710,141).

The disclosure of Ziegler has been set forth above. Particularly, Ziegler teaches the use of humectants such as polyols (glycerols, polyethylene glycols, etc.) to improve skin feel, reduce scaling, etc. The humectant is used in an amount of 1-15% and glycerol is preferred. See column 3, lines 20-40.

Ziegler does not teach aloe vera as the humectant.

Lin while teaching composition for treating wrinkles, teaches the use of humectants in the amount of 0.1-20% including polyols (glycerols, polyethylene glycols) and aloe vera. The preferred humectants are aloe vera gel or glycerol. See column 5, lines 59-65.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Ziegler and Lin and substitute the prior art's humectant with the instant humectant, aloe vera. One would have been motivated to do so since Lin teaches both glycerol and aloe vera gel function as humectant and skin conditioners in cosmetic compositions. Therefore, it would have been prima facie obvious for a skilled artisan to substitute one functional equivalent humectant with another equivalent since the prior art establishes the functional equivalency of both.

Claims 7, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ziegler (5,310,556) in further view of Enjolras (5,656,278) in further view of JP 11199461.

The disclosure of Ziegler has been set forth above. Ziegler teaches the composition for treating dry skin.

Ziegler does not teach the instant essential oils.

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JP '461 teaches a medical herbal cream for treating cracked palms and heels comprising 0.5-2 parts of an aromatic essential oil such as basil oil, peppermint oil, or chamomile oil; petroleum jelly, and a preservative such as rosemary in the amount of 10-20 parts. See abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the above references and further utilize the instant essential oils. One would have been motivated to do so with a reasonable expectation of success since both references are directed to treating dry skin and thus one would further add the instant essential oil to further provide a healing effect to prevent. With regard to the rosemary oil, one would have been motivated to add rosemary oil since Ziegler teaches the use of preservatives in the composition and JP teaches rosemary oil functions as a preservative.

Conclusion

All the claims are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Sharmila S. Gollamudi
Primary Examiner
Art Unit 1616

SSG